

AUG - 6 1999

510(k) Summary

K992406

Trade Name: VAPR™ 2.3mm End Effect Electrode

Sponsor: Mitek Products
60 Glacier Drive
Westwood, MA 02090
Registration #1221934

Contact Person: Paula E. Bulger
Manager, Regulatory Affairs
Mitek Products
60 Glacier Drive
Westwood, MA 02090
Phone: (781) 251-2746
Fax: (781) 461-9166

Date: July 21, 1999

Device Generic Name: Electrosurgical electrode

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Product Code: GEI (21 CFR 878.4400)

Predicate Devices: K974022 - Mitek VAPR™ T Thermal Electrode
K963783 - Mitek VAPR™ System

Product Description: The devices described in this 510(k) are sterile, disposable electrodes designed for use with the Mitek VAPR™ System.

Indications for Use:

The Mitek VAPR™ System, when used with a VAPR™ 2.3mm End Effect Electrode, is intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.

Safety and Performance:

This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's subcontractor Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the modified VAPT™ 2.3mm End Effect Electrodes have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 1999

Ms. Paula E. Bulger
Regulatory Affairs Manager
Mitek Products
60 Glacier Drive
Westwood, Massachusetts 02090

Re: K992406
Trade Name: VAPR™ 2.3mm End Effect Electrode
Regulatory Class: II
Product Code: GEI
Dated: June 19, 1999
Received: June 20, 1999

Dear Ms. Bulger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

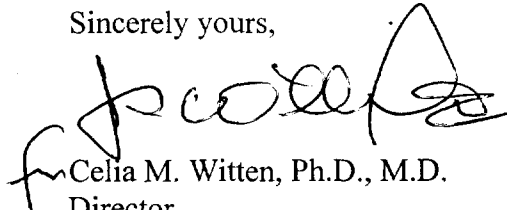
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Ms. Paula E. Bulger

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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510(k) Number (if known): K992406

Device Name: VAPR™ 2.3mm End Effect Electrode

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the -Counter Use


(Division Sign-Off)

Division of General Restorative Devices
510(k) Number K992406

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